SCHWIND
eye-tech-solutions
CARRIAZO-PENDULAR

K082043

510(k) Summary

AUG - 1 2008

Applicant:	SCHWIND eye-tech-solutions
Address:	Mainparkstrasse 6-10 Germany 63801 Kleinostheim
Manufacturer:	SCHWIND eye-tech-solutions GmbH & Co.KG Mainparkstrasse 6-10 Germany 63801 Kleinostheim Registration Number: 8010873
Telephone: Fax Number:	+49/6027 5080 +49/6027 508208
Contact Person:	Mr. Rolf Schwind
Preparation Date: (of the Summary)	May 2007
Device Name:	Carriazo-Pendular Microkeratome
Common Name:	Keratome (microkeratome)
Classification:	21 CFR 886.4370 Class I Product Code: HNO Panel: 86
Predicated Devices:	Carriazo-Pendular Microkeratome (K032910) BD K-4000™Microkeratome (K023092) INTRALASE FS Laser (K041893)

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Device Description:

The Carriazo-Pendular is an AC powered microkeratome.
Cutting head and blade are designed in a convex form similar to the cornea itself. Due to the unique pendulum motion of the Carriazo-Pendular, the cornea becomes more applanated in the center than in the periphery. This technology provides a homogeneous and predictable flap thickness and smooth cutting edges.

The Carriazo-Pendular consists of:

Carriazo-Pendular console:	The console controls and guards the cutting process and guides the surgeon through the use of the microkeratome. Additional parameters will be saved for later analysis.
Cutting heads:	Different heads are available in order to adjust for different flap thicknesses.
Suction rings:	The suction ring is necessary to fixate the eye during the cut. Different suction rings for different flap diameters are available. The hinge position can be freely selected (360 degrees).
Foot switches:	The foot switch starts the vacuum, and forward and backward movement of the microkeratome.
Monitoring software:	The software was developed for read out of relevant monitored data, which are stored during the operation in the Carriazo-Pendular console. These data can be used for quality insurance, supporting the doctor in the process of improving the cutting execution and analysis of potential cut complications.

Intended Use:

The Carriazo-Pendular Microkeratome is indicated for shaving the cornea prior to lamellar (partial thickness) transplant or to create a flap in the cornea.

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Technological Characteristics:

The Carriazo-Pendular is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Carriazo-Pendular (K032910), amongst others.

The new Carriazo-Pendular has the following similarities compared to the predicate Carriazo-Pendular (K032910):

- same intended use,
- same fundamental scientific technology and the same operating principle,
- same manufacturing processes,
- construction of identical materials.

Compared to the predicated Carriazo-Pendular (K032910) the new Carriazo-Pendular differs in the following features:

- additional cutting heads,
- different sterilization process,
- improved blade box,
- Pendular Monitoring Software.

Performance tests/data:

Test on pig eyes and clinical performance data on human eyes shows that the new cutting heads perform flaps similar to the existing heads except for the different flap thicknesses.
Functional testing, cleaning validation and biocompatibility tests demonstrate that the device performs as intended.

Conclusion:

Based on the information in the notification, SCHWIND eye-tech-solutions believes that Carriazo-Pendular Microkeratome is substantially equivalent to the claimed predicate devices and does not raise new questions in terms of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 1 2008

SCHWIND eye-tech-solutions
c/o Mr. Stefan Preiss
TÜV SÜD America Inc.
1775 Old Highway 8 NW
New Brighton, MN 55112-1891

Re: K082043

Trade/Device Name:	Carriazo-Pendular Microkeratome
Regulation Number:	21 CFR 886.4370
Regulation Name:	Keratome, AC-Powered (Microkeratome)
Regulatory Class:	I
Product Code:	HNO
Dated:	July 11, 2008
Received:	July 18, 2008

Dear Mr. Preiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082043

Device Name: Carriazo Pendular Microkeratrom

Indications for Use: The Carriazo Pendular Microkeratom indicated for shaving the cornea prior to lamellar (partial thickness) transplant or to create a flap in the cornea.

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Cocurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

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